UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: November 12, 2003

To: Dr. David Hoyt Mailcode: 8896

Re: Project #030443
A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection (Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme) When Used to Treat Patients in Hemmorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting

Dear Dr. Hoyt:

Your office asked that the HRPP Office supply you with the information regarding the community consultation for this project since this is a study that by regulation requires community consultation. The HRPP assisted you with fulfilling this requirement by setting up two opportunities for community input regarding this study.

The first community consultation was held on July 30th at 7 p.m. with a community panel. These individuals were invited to participate in this process based on the diversity of San Diego as a whole, and/or being part of the demographic profile of the types of individuals that might be a part of this study if it was approved for this site. The panel listened to a presentation by the PI and asked insightful and interesting questions. They asked about the DSMB for this study. Exactly what was a DSMB? Who's on it? Will all ethnic groups be included as participants in this study? They wanted to be assured that cultural, ethnic and language specificity and sensitivity were paid attention too. One individual was concerned that there be an appropriate educational outreach methodology used to reach the Latino community. They wanted to know about the training of the paramedics that will be a part of this study. They were particularly interested to find out that the paramedics in the field would be in radio contact with the investigators at the hospital and that they would confirm, via radio with the Trauma Center, that a particular patient should be enrolled in this study. They were also told that by California law the paramedics would have to be trained by the research team regarding this study and it's procedures. When the question and answer session finished there were no objections from any of the participants about the study and they felt that it should go forward.

The second opportunity for the community to voice their opinion regarding this study occurred on the evening of August 6th at the Medical Center Auditorium. Newspaper ads as well as Internet information had been posted about this study inviting the public to come to the presentation and ask questions or raise concerns. Again the PI gave a power-point presentation of the study and entertained questions and concerns from the audience. Interestingly enough four Jehovah Witnesses attended this community presentation. Their issue with this study was that they did not consider PolyHeme to be a blood fraction. Two out of the four of them filled out comment sheets and they said that they would not be part of this study based on their "belief in Bible Laws". The PI told them that they would supply a wristband for them to wear that stated that they did not want to participate in this study. They were not particularly interested in receiving the wristbands since they said that they currently carry a card with information concerning their objection to blood products in their wallets.

No one else who attended this community session voiced any concerns regarding this study going forward.

All of the information outlined in this correspondence was taken to the full IRB and played a part in their deliberations for this study.

Please let me know if the sponsor of this study requires any additional information regarding this process.

Sincerely,

Lucille Pearson, CIP, Deputy Director
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